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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/040,830	01/08/2002	Gary E. Borodic	33677-00000	2713

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EXAMINER

FORD, VANESSA L

ART UNIT	PAPER NUMBER
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1645

DATE MAILED: 11/26/2003

8

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Applicati n No.

10/040,830

Applicant(s)

BORODIC ET AL.

Examiner

Vanessa L. Ford

Art Unit

1645

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 24 July 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1-15 is/are pending in the application.
- 4a) Of the above claim(s) 3-7, 10 and 12-15 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1, 2, 8, 9 and 11 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☒ Claim(s) 1-15 are subject to restriction and/or election requirement.

## Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

## Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 5.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

## **DETAILED ACTION**

### ***Election/Restriction***

1. Applicant's election of Group I, species A, trigeminal neuralgia with traverse filed 24 July 2003 is acknowledged. Claims 12-14 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being to a non-elected invention and claims 3-7, 10 and 15 are withdrawn because they are drawn to a non-elected species. The election of species is traversed because of the election of a specific immunotype of botulinum toxin. Applicant urges that the initial experimentation of this invention was performed with botulinum A toxin however, there is high probability of effectiveness with other immunotypes including types A-G. Applicant's argument is not found persuasive because botulinum toxin A-G are independent and distinct immunotypes of botulinum toxin. However, upon allowance of a generic claim, Applicant will be entitled to other species or at least consideration of other species. If no generic claim is held allowable, then Applicant will not be entitled to additional species. Therefore, claims 1-11 and 15 are to a plurality of disclosed patentably distinct species and Applicant is required under 35 U.S.C. 121 to elect a single disclosed species embraced by the claimed genus. The requirement is deemed proper and is therefore made FINAL.

### ***Claim Objections***

2. The numbering of claims is not in accordance with 37 CFR 1.126 which requires the original numbering of the claims to be preserved throughout the prosecution. Misnumbered claims 1-14 have been renumbered as claims 1-15.

***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

3. Claims 1, 8-9 and 11 are rejected under 35 U.S.C. 102(e) as anticipated by  
~~Aoki~~  
~~Binder~~ (U.S. Patent No. 6,464,986, published October 15, 2002).

Claims 1, 8-9 and 11 are drawn to a method of treating pain caused by neuralgia comprising administering botulinum toxin to an afflicted area of a patient.

Aoki et al teach a method of treating pain caused by posttherapeutic neuralgia (column 24, Example 3). Aoki et al teach that the patient was administered between 50 and 200 units of botulinum toxin A and within 1-7 days after neurotoxin administration patient's pain was substantially alleviated (column 24, Example 3). Claim limitation "wherein the neuralgia is associated with trauma" would be inherent in the teaching of the prior art because neuralgia is associated with trauma and pain. Aoki et al anticipates the claimed invention.

Since the Office does not have the facilities for examining and comparing applicant's method with the method of the prior art, the burden is on the applicant to

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show a novel or unobvious difference between the claimed method and the method of the prior art (i.e., that the method of the prior art does not possess the same material method steps and parameters of the claimed method). See In re Best, 562 F.2d 1252, 195 USPQ 430 (CCPA 1977) and In re Fitzgerald et al., 205 USPQ 594.

4. Claims 1-2, 8-9 and 11 are rejected under 35 U.S.C. 102(b) as anticipated by Binder (*U.S. Patent No. 5,714, 468, published February 3, 1998*).

Claims 1-2, 8-9 and 11 are drawn to a method of treating pain caused by neuralgia comprising administering botulinum toxin to an afflicted area of a patient.

Binder teaches a method of treating pain caused by trigeminal neuralgia by delivering an invertebrate presynaptic neurotoxin (botulinum toxin A) to a mammal (see the Abstract). Binder teaches that the botulinum toxin A is administered to the muscles of the face, cranium and neck (see the Abstract). Binder teaches that neurotoxin can be administered in a dose up to about 1000 units although individual dosages of about 15-30 units are preferred and dosages of 2.5 to 5 units will have therapeutic efficacy. Binder teaches that the neurotoxin will be administered as a composition at a dosage that is proportionally equivalent to about 2.5 cc/100 units (see columns 5-6). The claim limitation "wherein the neuralgia is associated with trauma" would be inherent in the teaching of the prior art because trigeminal neuralgia is associated with trauma and pain. Binder anticipates the claimed invention.

Since the Office does not have the facilities for examining and comparing applicant's method with the method of the prior art, the burden is on the applicant to

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show a novel or unobvious difference between the claimed method and the method of the prior art (i.e., that the method of the prior art does not possess the same material method steps and parameters of the claimed method). See In re Best, 562 F.2d 1252, 195 USPQ 430 (CCPA 1977) and In re Fitzgerald et al., 205 USPQ 594.

### ***Status of the Claims***

5. No claims allowed.

### ***Conclusion***

6. Any inquiry of the general nature or relating to the status of this general application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Papers relating to this application may be submitted to Technology Center 1600, Group 1640 by facsimile transmission. The faxing of such papers must conform with the notice published in the Office Gazette, 1096 OG 30 (November 15, 1989). Should applicant wish to FAX a response, the current FAX number for the Group 1600 is (703) 308-4242.

Any inquiry concerning this communication from the examiner should be directed to Vanessa L. Ford, whose telephone number is (703) 308-4735. The examiner can normally be reached on Monday – Friday from 9:30 AM to 6:00 PM. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Lynette Smith, can be reached at (703) 308-3909.



Vanessa L. Ford  
Biotechnology Patent Examiner  
November 20, 2003



**LYNETTE R. F. SMITH**  
**SUPERVISORY PATENT EXAMINER**  
**TECHNOLOGY CENTER 1600**